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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

ROBERT L. APTER, *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 3:22-cv-184

JUDGE JEFFREY V. BROWN

**Defendants' Reply in Support of Their Renewed Motion to Dismiss the
Amended Complaint**

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INTRODUCTION

Defendants' renewed motion to dismiss explained why the Court lacks subject-matter jurisdiction over Plaintiffs' *ultra vires* claim, which all parties agree is the sole surviving claim in this case. None of the Plaintiffs has standing to challenge FDA's Statements as *ultra vires*. Although Plaintiffs' Opposition advances six theories of injury, none of them withstand scrutiny.

For starters, Plaintiffs still have not met their burden of demonstrating an injury in fact. Plaintiffs' own statements reveal that Bowden and Marik resigned voluntarily, not under duress as the Opposition argues – and self-inflicted injuries do not suffice for standing. Similarly, if Bowden spends less than an hour each month talking to pharmacists about ivermectin prescriptions, that does not amount to a cognizable injury; it is ordinary medical practice. Likewise, Plaintiffs' Opposition fails to salvage any injury based on alleged interference with the practice of medicine, a speculative increased exposure to malpractice liability, Bowden's purported reputational harm, or Apter's referral to state medical boards. These failures are fatal to standing.

Plaintiffs likewise have not shown any claimed injury was the predictable result of the Statements and therefore fairly traceable to them. Moreover, they offer nothing but speculation about how the relief they seek – limited changes to the Statements – would likely remedy any of their asserted injuries.

ARGUMENT

Plaintiffs' Opposition offers six theories of injury: The Statements allegedly (1) caused Bowden and Marik to resign under duress, (2) resulted in Apter being referred for disciplinary proceedings, (3) interfered with Apter's and Bowden's practice of medicine, (4) caused Bowden reputational harm, (5) caused Bowden

economic harm, and (6) increased Apter's and Bowden's exposure to medical malpractice liability. ECF No. 61 (Opp'n) at 13–21. Each theory is meritless. And Plaintiffs have “waived” any other “argument[] in favor of standing.” *E.T. v. Paxton*, 41 F.4th 709, 718 n.2 (5th Cir. 2022) (emphasis and quotation omitted). Thus, Plaintiffs have not met their burden, either through the allegations in the Amended Complaint or with a showing by a preponderance of the evidence, that they face an injury-in-fact that is fairly traceable to the Statements and likely redressable by the requested relief. *See* ECF No. 59 (R-MTD) at 16.

I. Redressability Is Not Presumed, and Plaintiffs Cannot Show It

Beginning at the end, Plaintiffs are wrong that “redressability is presumed” if they establish an injury fairly traceable to the Statements. Opp'n 28. To be sure, when governmental action *directly* causes a claimed injury, enjoining the governmental action in question will “usually” redress that injury. *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 n.1 (D.C. Cir. 2017). However, if “the new status quo is held in place by other forces” – such as when the challenged governmental action is only one of many causes of a claimed injury – the “undoing of the governmental action” in question “will not undo the harm[].” *Renal Physicians Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 489 F.3d 1267, 1278 (D.C. Cir. 2007). That is particularly the case where, as here, Plaintiffs' claim to redressability rests on ““the unfettered choices made by independent actors not before the court[] and whose exercise of broad and legitimate discretion the court[] cannot presume either to control or predict.”” *E.T.*, 41 F.4th at 720 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992)).

The narrow relief Plaintiffs seek on the *ultra vires* claim would not redress their claimed injuries. Specifically, they seek a declaration that FDA's statements

that “direct[] or opin[e] on whether ivermectin should be used for certain off-label purposes” are unlawful, and equitable relief preventing FDA from making such statements. ECF No. 12 (Am. Comp.) at 43–44. Importantly though, after the Fifth Circuit’s decision in this case, the only agency conduct remaining at issue is FDA’s *recommendations* about using ivermectin to prevent or treat COVID-19, *not* any of the *information* provided in the Statements. *See* R-MTD 26–30.

So, if Plaintiffs were to prevail, the article titled “Why You Should Not Use Ivermectin to Treat or Prevent COVID-19” could be renamed “Ivermectin Is Not FDA Approved or Authorized to Treat or Prevent COVID-19” and retain, for example, content on the drug’s risks and how “[c]urrently available data do not show ivermectin is effective against COVID-19.” *See* Ex. 1. Plaintiffs’ requested relief would leave much of the Statements’ content untouched.

Plaintiffs can only speculate that such limited revisions would “likely” change third parties’ scientific understanding about the use of ivermectin to prevent or treat COVID-19, or convince third parties to reverse the actions that allegedly harmed Plaintiffs. *See* R-MTD 27–28. Plaintiffs’ redressability argument is especially speculative because it relies on multiple layers of “independent actors” not before the Court with discretion that the Court could not “control or predict.” *E.T.*, 41 F.4th at 720.

For example, the joint statement of the American Medical Association (AMA), the American Pharmacists Association (APhA), and the American Society of Health-System Pharmacists (ASHP) was prompted by their “alarm[]” about the recent “exponential[]” increase in prescriptions. Ex. 25 at 2. It invokes the conclusion of multiple independent organizations — the National Institutes of

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Health (NIH), the World Health Organization (WHO), and Merck (the drug's sponsor) – that there is “insufficient evidence” to support using ivermectin to treat COVID-19, and notes that the Infectious Diseases Society of America (IDSA) recommended against using it outside of a clinical trial. Ex. 25 at 2–3. It then advises that using ivermectin to treat COVID-19 “has been demonstrated to be harmful to patients.” *Id.* at 3. The joint statement links to FDA’s article as “indicating that ivermectin is not authorized or approved” to prevent or treat COVID-19 and only refers the reader to the article “[f]or more information.” *Id.*

Even if this Court were to conclude that FDA lacked legal authority to make recommendations about ivermectin to consumers, Plaintiffs rely on pure conjecture when they contend that modifying FDA’s Statements would cause organizations like the AMA, the APhA, the ASHP, the NIH, the WHO, the IDSA, and Merck to suddenly “change course,” Opp’n 29 (citing the joint statement), and revise their statements and guidelines. The requested relief is similarly unlikely to alter the assessment of the scientific evidence by sophisticated healthcare entities like hospitals, boards of medicine, or pharmacies, particularly since the relief would be based on an issue of statutory authority, not science.

Plaintiffs also suggest that they can meet their burden to show redressability because FDA “intended” the Statements to “precipitat[e]” Plaintiffs’ claimed injuries. Opp’n 3, 28–29. Plaintiffs misidentify FDA’s intent in making the Statements. As is clear from the face of the Statements, FDA’s intent was to inform consumers, not injure Plaintiffs. *See, e.g.,* Ex. 1.

In sum, Plaintiffs have failed to meet their burden of showing it is likely the requested relief would cause the third parties who allegedly injured them to change course in a manner that would likely redress Plaintiffs' alleged injuries.

II. Plaintiffs' Theories of Standing Are Meritless

A. Bowden and Marik voluntarily resigned

Plaintiffs now assert, without elaboration, that their resignations were "under duress." Opp'n 20. Bald assertions will not suffice; Plaintiffs are "obliged to submit facts through some evidentiary method to sustain [their] burden of proof." *Superior MRI Servs., Inc. v. All. Healthcare Servs., Inc.*, 778 F.3d 502, 504 (5th Cir. 2015) (quotation omitted). And here, the evidentiary record contains Bowden's and Marik's admissions that they voluntarily resigned. Exs. 9 ¶ 7 (Bowden's declaration stating that she "voluntarily resigned"), G at 47 (Bowden resigned to "shift[]" her "practice" to treat unvaccinated patients), O at 2 (Marik resigned to "focus [his] attention and energy" on "other interests"); *see also* R-MTD 10-14; Ex. R (CEO's statement that "Dr. Bowden voluntarily resigned"). Such "self-inflicted injur[ies]" cannot support their standing. *Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 541 (5th Cir. 2019).

Furthermore, Bowden's and Marik's resignations are not fairly traceable to the Statements' recommendations. Plaintiffs' contention that the "timing" of their decisions "highlights" the Statements' role in those decisions, Opp'n 21, suffers from the "*post hoc ergo propter hoc* fallacy," which wrongly "assumes causality from temporal sequence," *Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009). Indeed, the evidence disproves Plaintiffs' "false inference." *Id.* For example, Bowden resigned from Houston Methodist Hospital after she was suspended for, among other things, disrespectful and vulgar behavior. Ex. R at 4. And Plaintiffs

do not show how Sentara's guidelines about ivermectin constitute "duress," let alone "precipitated" Marik's resignation, Opp'n 24, when the guidelines did not prohibit doctors from prescribing ivermectin elsewhere or from encouraging their patients to use ivermectin, Ex. N at 122, 138; *see also* Ex. O.

Plaintiffs misconstrue Defendants' earlier filing when they claim that FDA "conceded" that the Statements *in fact* indirectly caused third parties to take actions that injured Plaintiffs. Opp'n 22 (citing ECF No. 25 at 15). What Defendants argued is that standing "is ordinarily substantially more difficult to establish" when, as in this case, "a causal relation between injury and challenged action depends upon the decision of an independent third party." ECF No. 25 at 16 (quoting *Daves v. Dallas Cnty.*, 22 F.4th 522, 542–44 (5th Cir. 2022) (en banc)). Defendants have always maintained that Plaintiffs have failed to establish an injury fairly traceable to the Statements. *See, e.g.*, R-MTD 19–23.

Finally, neither Bowden nor Marik makes any redressability argument specific to their resignations, and they express no desire to resume working for their former employers. *See* Opp'n 28–30. Alterations to the Statements would not reverse their resignations.

B. [REDACTED]

Plaintiffs do not dispute Defendants' observation that a physician is not injured merely by being referred to a state medical board or that any claims based on the referrals are moot. *See* R-MTD 18, 29; Opp'n 20. Instead, they argue that Apter's referrals to state medical boards are injuries because he was "'engaged in a course of [protected] conduct'" and told "'to stop'" or else face "'disciplinary action.'" Opp'n 20 (quoting *Kiser v. Reitz*, 765 F.3d 601, 608 (6th Cir.

2014)). But neither the Amended Complaint nor Plaintiffs' brief identify the conduct at issue, establish that it is protected, or allege that Apter was ever told to cease that conduct by a disciplinary board or anyone else. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs do not argue that these allegations concern protected conduct.

Plaintiffs suggest that the time and expense expended in Apter's defense constitutes an injury, Opp'n 20, but this argument is not supported by any allegation in the Amended Complaint or any exhibit. Regardless, Plaintiffs do not dispute Defendants' point that "[h]aving to defend oneself in a legal proceeding ordinarily does not give rise to a redressable injury." R-MTD 18 (quoting *Simic v. City of Chi.*, 851 F.3d 734, 739 (7th Cir. 2017)); see also *Gulfport Energy Corp. v. FERC*, 41 F.4th 667, 677 (5th Cir. 2022) ("time and resources" expended in a defense to an agency proceeding is not a cognizable injury).

Plaintiffs also fail to establish traceability or redressability with respect to the referrals. Contrary to Plaintiffs' assumption, Opp'n 20, the referrals' mere mention of FDA does not show they were a "predictable" response to FDA's Statements, none of which tell physicians not to prescribe ivermectin or pharmacists to refrain from filling prescriptions. *Daves*, 22 F.4th at 543. And while the Washington complaint notes that ivermectin prescriptions were receiving additional scrutiny at that pharmacy, Ex. B at 4, Apter was not referred

because he failed to provide a non-COVID medical reason for the prescription. Opp’n 20. In fact, Apter *did* provide a non-COVID medical reason for the prescription: scabies. Ex. B at 4. The concern was the apparent absence of any documentation of the prescription or of a valid doctor-patient relationship. *Id.* Those issues were plainly untraceable to FDA’s Statements. Plaintiffs cannot show redressability for the same reason: [REDACTED]

C. The Statements’ claimed impact on Apter’s and Bowden’s practice of medicine does not support standing

Defendants’ motion explained that Plaintiffs’ “interference with the practice of medicine” theory is vague and conclusory, and at most is a misguided attempt to invoke the interests of Apter’s and Bowden’s patients.¹ R-MTD 24–25.

Plaintiffs’ attempts to resuscitate this theory of injury are unpersuasive.²

1. Abstract injury to the “practice of medicine” is not cognizable

Plaintiffs ground their theory of “injury to their practice of medicine” in a hodgepodge of sources: a state rule of evidence protecting certain confidential communications between doctors and patients, the notion that physicians determine the best course of action for their patient, and a federal statute regarding medical devices. Opp’n 13–14. But even if these authorities recognize

¹ Plaintiffs do not dispute that because Marik is no longer licensed, *see* Ex. 10 at 10, he could not suffer an injury to his nonexistent practice of medicine.

² Plaintiffs mischaracterize the Fifth Circuit’s decision when claiming it “already concluded” that FDA “interfere[ed] with the practice of medicine.” Opp’n 15 (citing *Apter v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, 588–89, 595 (5th Cir. 2023)). Actually, the Fifth Circuit ruled only that Plaintiffs had “plausibly alleged” the Statements went beyond FDA’s “authority to inform, announce, and apprise.” *Apter*, 80 F.4th at 595.

the doctor-patient relationship in the abstract, the Supreme Court has rejected Plaintiffs' notion that a claimed violation of a legal principle is always a cognizable injury.³ *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425–26 (2021).

Plaintiffs also argue that, since courts recognize recreational and aesthetic injuries, courts must also recognize “interference with a vocation” as an injury. Opp’n 13. But recreational and aesthetic injuries are personal to the plaintiff. Not so with Plaintiffs’ novel “practice of medicine” theory, which would allow them to satisfy Article III without any direct effect on themselves (Plaintiffs always could prescribe ivermectin) and with only derivative effects on third party patients (such as when non-party “[i]nsurance companies” refuse to pay a claim for an ivermectin prescription). Opp’n 14. Unsurprisingly, Plaintiffs cite no support for this breathtakingly expansive view of standing.

Finally, Plaintiffs argue that they have identified a “common-law analogue for their asserted injury”: tortious interference with a doctor-patient relationship. Opp’n 16–17 (quoting *TransUnion*, 594 U.S. at 417). But the cases cited in Plaintiffs’ brief reveal, the “harm” recognized in that cause of action is “economic” (not an injury to the abstract relationship itself), *Regents of the Univ. of Cal. v. Aisen*, 2016 WL 1428072, at *7 (S.D. Cal. Apr. 12, 2016), and the tort requires proof that the defendant acted with “malice,” *Garcia v. Home Depot USA, Inc.*, 1999 WL 362787, at *6 (N.D. Tex. June 2, 1999). It does not describe an injury that is analogous to Plaintiffs’ abstract “interference with the practice of medicine” theory.

³ The statute Plaintiffs cite, 21 U.S.C. § 396, by its own terms has no application here. See ECF No. 42 at 3–5.

2. Apter and Bowden cannot rely on claimed injuries to their patients

Plaintiffs try to rely on injuries to third party patients, Opp’n 15–16, but Plaintiffs indisputably must first establish their own standing. R-MTD 25 (citing *Ward v. Santa Fe Indep. Sch. Dist.*, 393 F.3d 599, 606 (5th Cir. 2004)). The third-party standing doctrine, after all, “does not eliminate the distinct and independent requirement of Article III that the dispute between the parties must amount to a case or controversy.” *Nat’l Fed’n of the Blind of Texas, Inc. v. Abbot*, 647 F.3d 202, 210 (5th Cir. 2011). Plaintiffs themselves lack standing, so any argument about unknown patients’ injuries is irrelevant. What’s more, Plaintiffs do not dispute Defendants’ observation that patients “do not have to seek legal recourse” since they “are able to get their ivermectin prescriptions filled.” R-MTD 25; see <https://perma.cc/AAU4-ZBCL>.

Plaintiffs claim a special exception to the rule against third-party standing for “providers to invoke the rights of their actual or potential patients.” Opp’n 16 (quoting *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118 (2020)). But that principle was expressly limited to challenges by “abortion providers” to “abortion-related regulations.” 140 S. Ct. at 2118. Abortion is “a very special context,” and “third party standing should not be extended to all cases where a physician seeks to assert some constitutional violation that the patients could bring themselves.” *Massey v. Helman*, 35 F. Supp. 2d 1110, 1116 (C.D. Ill.), *aff’d*, 196 F.3d 727 (7th Cir. 1999).

3. Plaintiffs cannot show traceability or redressability

Even if Plaintiffs’ “interference with practice of medicine” theory were cognizable, they fail to show their injury is fairly traceable to the Statements’

recommendations or likely redressable by their requested relief. Plaintiffs can only tie the Statements to their practice of medicine only through an implausible chain of decisions by independent third parties, *i.e.*, sophisticated entities like pharmacists, hospitals, and medical boards, which exercise their own independent scientific judgment. Those entities' decisions and actions were not a "predictable" response to any recommendations *to consumers* in the Statements and, as discussed, Plaintiffs have not shown that it is likely that the requested relief would change the conduct of those sophisticated actors. Plaintiffs' argument to the contrary is impermissible "speculation." *Daves*, 22 F.4th at 543.

Plaintiffs' citation to a letter FDA sent to two professional organizations, the Federation of State Medical Boards and the National Association of Boards of Pharmacy, does not suggest otherwise. The letter embeds a link to the article regarding known side effects of ivermectin and does not say anything about whether physicians can prescribe ivermectin to prevent or treat COVID-19. Instead, the letter explains that "FDA has received complaints about compounding pharmacies selling drug products containing ivermectin, claiming that they can treat or prevent COVID-19." Ex. 22. In any event, those organizations are not "sovereign regulatory bod[ies]," so Plaintiffs' reliance on FDA's letter to them "confirms the central problem with [their] standing theory: The theory rests on pure guesswork about the decisions of parties not before the [C]ourt." *Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 546 (6th Cir. 2021) (citing *Clapper v. Amnesty Int'l*, 568 U.S. 398, 413 (2013)).

In short, any "practice of medicine" injury is not redressable because it is pure conjecture that the limited modifications Plaintiffs seek to the Statements —

which were among many statements made in the scientific community – would change the independent third parties’ scientific understanding of the risks and benefits of using ivermectin to prevent or treat COVID-19 or convince the third parties to reverse the actions that allegedly harmed Plaintiffs. *See supra* pp. 2–5.

D. Bowden’s alleged reputational injury does not support standing

Bowden argues she “suffered reputational harm,” based on two social media posts by private citizens. Opp’n 18–19 (citing Exs. 23, 24). But the mere existence of a third party’s derogatory statement on the internet does not translate to a reputational injury sufficient for standing. *Contra id.* 19. Conspicuously, neither the Amended Complaint nor Bowden’s declarations even allege in more than bare conclusory fashion – let alone establish by a preponderance of the evidence – that these social media posts or anything else harmed her reputation. *See* Am. Comp. ¶ 105; Exs. 9, 29 (Bowden declarations).⁴

Plaintiffs also fail to establish that any reputational injury from third-party social media posts is fairly traceable to the Statements (which do not mention Plaintiffs) or redressable. They argue only that the social media posts “have referenced” the Statements. Opp’n 24. That falls far short of establishing by a preponderance of the evidence that Bowden’s alleged reputational injury was the “predictable” effect of the Statements. Plaintiffs likewise do not explain how their requested relief would ameliorate Bowden’s supposed reputational injury caused by the social media posts. For example, Plaintiffs do not suggest that the users “@LoveLogCabins” (whose account appears to have been deleted) or

⁴ Plaintiffs assert that they “have suffered reputational harm” but only cite exhibits regarding Bowden. Plaintiffs have thus waived any standing argument based on reputational harm to Apter or Marik. *E.T.*, 41 F.4th at 718 n.2.

“@rx0rcist” would alter the content of their posts in response to the limited modifications to the Statements that Plaintiffs request. And Bowden has placed the blame for alleged harm to her reputation squarely on the shoulders of Houston Methodist Hospital and its CEO. Bowden alleged that the hospital held “extreme and unrelenting bias” and “spite” towards her practice and “severely compromised” her reputation via “intentionally false statements” spread “in the broadest manner possible.” Ex. L ¶¶ 11, 25(d)&(e).

E. Bowden’s claimed economic harm does not support her standing

Bowden also claims that the Statements caused her economic harm. Opp’n 17–18. Yet her unsworn “Supplemental Declaration” states only that, with decreasing frequency, she speaks to pharmacists a few times a month for about 15 minutes regarding her ivermectin prescriptions, which she says takes time away from her other responsibilities. Ex. 29. Notably, Bowden does *not* state these calls cause her economic harm, much less provide facts about the financial impact. *See id.* Plaintiffs simply offer no evidence of any concrete financial injury.

Bowden’s alleged injury is unlike the one addressed in *Alliance for Hippocratic Medicine v. FDA*. *Contra* Opp’n 17–18. In *Alliance*, the plaintiff doctors claimed they would be required, over their conscience objections, to devote significant time to “provid[e] emergency treatment” to patients who had been prescribed an allegedly unsafe drug by other doctors. 78 F.4th 210, 229, 232–33 (5th Cir. 2023), *cert granted*, Nos. 22-235, 22-236 (U.S.). Here, by contrast, Bowden chooses to prescribe ivermectin with full awareness that, as with any prescription, some pharmacists may have questions and contact her to discuss. *See* 22 Tex. Admin. Code § 291.29 (Professional Responsibility of Pharmacists); *see also* <https://perma.cc/8KCG-YS59> (September 2021 joint statement of the Texas

Medical Board and Texas State Board of Pharmacy stating that drugs were “permitted to be prescribed off-label” and that it was in the “professional judgment” of physicians to write prescriptions and of pharmacists to dispense them). Aside from marshalling no evidentiary support, Plaintiffs have cited no authority that Bowden’s calls with pharmacists are a justiciable injury rather than one of the basic responsibilities of being a physician.

Bowden’s economic injury theory also has the same traceability and redressability defects as Plaintiffs’ other theories. The recommendations to consumers in FDA’s Statements would not predictably impact pharmacists’ exercise of their individual professional discretion, and it is pure speculation that the limited modifications to the Statements Plaintiffs seek would impact the views of any pharmacists who are resistant to filling Bowden’s prescriptions.

F. Allegedly increased exposure to malpractice liability does not grant Apter or Bowden standing

Plaintiffs allege that the Statements “expose[]” them to “increased liability for their continued prescribing of ivermectin” because one court cited one of FDA’s Statements when “determin[ing]” an element of medical malpractice. Opp’n 18. But this theory of injury rests on a “highly attenuated chain of possibilities” insufficient to demonstrate an injury-in-fact. *Louisiana v. Biden*, 64 F.4th 674, 682 (5th Cir. 2023) (quoting *Clapper*, 568 U.S. at 410). Apter and Bowden⁵ tout their successful treatment of thousands of patients with ivermectin, Exs. 8 ¶ 6, 9 ¶ 5, but do not claim to have faced a single malpractice allegation. It is entirely speculative that Apter or Bowden will face an ivermectin-

⁵ Because Marik is not a licensed physician, *see* Ex. 10 at 10, he does not have malpractice liability exposure that could be increased.

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related malpractice allegation in the future and, even if they did, they offer no evidence that any court would find prescribing ivermectin to be malpractice. Indeed, Plaintiffs do not cite a *single* case where a physician has *ever* been found liable for malpractice based on off-label use of ivermectin. *See* Opp’n 9 (collecting cases concerning whether hospitals could be compelled to administer ivermectin to patients with COVID-19). Plaintiffs’ “increased exposure to malpractice liability” theory is simply too speculative to constitute a cognizable injury, let alone establish the other elements of standing.⁶

CONCLUSION

The Amended Complaint should be dismissed for lack of subject matter jurisdiction.

⁶ Plaintiffs’ only source purporting to connect malpractice liability to the Statements is a trial court decision declining to order a hospital to administer ivermectin to a patient, not a medical malpractice case. Opp’n 18 (citing *DJC for DAC v. Staten Island Univ. Hosp.-Northwell Health*, 157 N.Y.S.3d 667, 673 (N.Y. Sup. Ct., Richmond Cnty. 2021)). There, the court found “persuasive” physicians’ affidavits that ivermectin should not be administered to a patient, since the patient was “not suffering from an active COVID-19 infection” but instead from bacterial pneumonia, which is not treated with ivermectin. *DJC for DAC*, 157 N.Y.S.3d at 673. And that court cited FDA’s article for the proposition that “there is no current evidence to justify off-label use of Ivermectin at this time,” *id.*, a proposition not at issue in this case. *See* Am. Comp. ¶ 3 (“This case is not about whether ivermectin is an effective treatment for COVID-19.”); *Apter*, 80 F.4th at 588–89 (noting that Plaintiffs’ *ultra vires* claim does not concern FDA’s authority to “issue *information*” but its authority to make “*recommendations*”). That case does not show that Apter and Bowden face a “*certainly impending*” injury, *James v. Hegar*, 86 F.4th 1076, 1081 (5th Cir. 2023), let alone an injury traceable to the recommendations in the Statements or redressable by limited alterations to those Statements.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

February 14, 2024

/s/ Isaac C. Belfer
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